

Best Evidence Statement Development Process Manual

3rd Edition, Revised



Created by the **CCHMC EVIDENCE COLLABORATION**

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LEGEND Evidence Evaluation Tools (*Let Evidence Guide Every New Decision*)

[Evaluating the Evidence Algorithm](#)

[Evidence Appraisal Forms](#)

[Table of Evidence Levels](#)

[Grade for a Body of Evidence](#)

[Judging the Strength of a Recommendation](#)

[LEGEND Glossary](#)

BEST EVIDENCE STATEMENTS (BESt)

The Best Evidence Statement (*BESt*) process was developed to provide an efficient way to share evidence regarding a specific health question or issue. A BESt answers a specific health or clinical question. Each BESt is designed to assure evidence is captured through a high-quality process using a standardized format and to provide a resource that informs evidence-based decision making (*EBDM*) at the point of care (*POC*) (*Appendix 1 BESt Template, Appendix 2 User Checklist*).

Possible reasons to develop a BESt include, but are not limited to:

- A key patient issue has been identified (*e.g., clinical, safety*)
- The care being provided to a specific patient population may not be based on the best available evidence
- The outcomes for a specific patient population are less than ideal
- There is variation in practice
- There is new evidence to be considered for a product, drug, or device
- There are questions concerning a product, drug, or device currently in use
- Patients/families are dissatisfied with specific care or outcomes
- There are potential benefits to efficiency and cost-effectiveness, if practice is changed
- There is an absence of CCHMC evidence-based documentation that addresses the issue (*e.g., guidelines, other BESts, policies/procedures, Knowing Notes, or Health topics*)
- There is alignment of the identified issue with strategic initiatives

Producing and implementing a BESt requires time and careful consideration of resources. With a manager responsible for budgetary decisions, discuss whether resources are available to support the development and potential implementation and monitoring of the evidence-based practice change that may result from this evidence exploration process.

The development of a BESt is a rigorous process of evaluating current evidence, which will either validate or suggest a need for change in current practice. Implementation of the evidence and care recommendations follows development of the BESt; and it is important to consider implementation throughout the development process. Implementation considerations might include:

- There is enough evidence to support a practice change; if not, consensus has been attained.
- The benefits of and resources required for the practice change outweigh the financial investment.

In order to ensure success and improve outcomes, you must select and engage team members, develop an evidence-based care recommendation, identify measures, plan for implementation, and evaluate and monitor the outcomes. Developing evidence statements without a process for use and sustainment may not promote a change in practice.

The maintenance of a BESt includes ongoing literature search and review of evidence to ensure content validity of the BESt. The BESt may need to be revised when new evidence indicates the need for modification. Team leader responsibilities include BESt maintenance, unless otherwise delegated to another team member.

At CCHMC, tools for working with a team to identify the BESt topic, areas for improvement, responsibilities, and expected outcomes may be found at the following webpages:

- [Quality Improvement Tools](#) (*e.g., key driver diagram, PDSA test cycles*)
- [Other Resources](#) (*e.g., team charter*)

SELECTION OF TEAM LEADER & MEMBERS

Identification of a multidisciplinary team, including key stakeholders, increases likelihood of successful development and implementation of each BEST. Benefits include team discovery of new evidence, collaborative solutions for use of new evidence in care/decisions, team perspectives from a variety of disciplines, families, or patients, and reduced bias in recommendation statements.

Multidisciplinary Team

A. Team Leader / Author

1. Identification

- a. Has available resources *(e.g., time, commitment, administrative staff)*
- b. Has motivation
- c. Possesses skills to guide a team
(e.g., leadership skills, communication skills, organizational skills)
- d. Can interface with relevant parties to communicate progress

2. Roles & Responsibilities

- a. Identify and disclose personal conflicts of interest
 - b. Assists in recruiting a development team *(i.e., Stakeholders and Team Members)* to balance conflicts of interest that may have undue influence on recommendations
 - c. Keeps process moving and on track
 - d. Coordinates development of the BEST
 - e. Coordinates meetings
 - f. Maintains the body of evidence through ongoing literature search and review to ensure content validity of the BEST
- If non-CCHMC staff or students are involved in the development of the BEST, a CCHMC employee must do the following:
 - a. serve as the Team Leader/Author
 - b. be actively engaged in the development process
 - c. provide oversight throughout the process
 - d. function as the point-of-contact with the Evidence Collaboration
 - e. be responsible for quality and initial development
 - f. be responsible for revision of the BEST (see Maintaining the Evidence)

B. Team Member / Co-Author

1. Identification

- a. Meets Content Reviewer Criteria [\(See below\)](#)
PLUS is involved in the development of the care recommendation
- b. Has available resources
(e.g., time to attend meetings and relay information to constituents, support and commitment from manager for the work required)
- c. Has the commitment to complete assignments
(e.g., time and skills for critical appraisal, searching for further evidence, drafting recommendation statements, providing feedback on developing draft)

2. Roles and Responsibilities

- a. Identify and disclose personal conflicts of interest
- b. Completes assignments, such as critical appraisal (*i.e., evidence evaluation*) or drafting recommendation statements
- c. Communicates work to those he/she represents, serving as a representative of colleagues who are not present at meetings
- d. Informs team leadership of unavoidable absences and keep oneself informed of team progress

C. Patient/Family/Parent or Other Parent Representative

1. Identification

- a. Has interest/experience in the clinical topic
(*e.g., parent, patient, family*)
- b. Represents a Parent Organization
(*e.g., Family Advisory Council, external parent organizations or foundations, parent support groups*)

2. Roles & Responsibilities

- a. Identify and disclose personal conflicts of interest
- b. Verifies topic is of interest for patients/parents
- c. Provides feedback from the patient/parent perspective
(*e.g., adherence, cost, feasibility, generalizability, accuracy, value/attitudes/beliefs*)

Other BEST Development Support

D. Content Reviewers:

1. Identification

- a. Are invested in this topic, question, issue, or concern
(*e.g., family members, inter-professional staff, business units, community, researchers, managers or supervisors*)
- b. Oversees or provides care or decision making for this population

2. Roles and Responsibilities

- a. Review BEST for subject matter content
- b. Advise as needed
- c. Identify and disclose personal conflicts of interest

E. Support / Consultant

1. Identification

- a. Anderson Center for Health Systems Excellence – Evidence-Based Decision Making (*EBDM*)
- b. Center for Professional Excellence – Evidence-Based Practice (*EBP*) and Research
- c. Edward L. Pratt Research Library
- d. Others – management, administrative assistants
– quality improvement coordinators, clinical outcomes managers, data analysts
– others trained in EBDM

2. Roles & Responsibilities

- a. Identify and disclose personal conflicts of interest
- b. Provide assistance, as needed, to team leader or members
- c. Assist with and/or teach literature search and search methods
- d. Provide expertise in evidence evaluation

CARE RECOMMENDATION DEVELOPMENT PROCESS

The development process includes working through the five steps of evidence evaluation:
(Appendix 3 – Overall Process Algorithm)

- **Developing a clinical question (Step 1):**
The clinical question identifies the patients or population, intervention(s), comparison, and outcome(s) which define the criteria for an electronic literature search.
- **Conducting a literature search (Step 2):**
A systematic search of the literature is conducted to find all relevant articles for a given topic.
- **Evaluating and appraising the individual studies/articles (Step 3):**
Evaluation of the evidence includes critically appraising each study included in the project.
- **Synthesizing the evidence (Step 4):**
Individual studies are synthesized, describing how the studies relate to the recommendation.
- **Developing a care recommendation (Step 5):**
The care recommendation is developed as the answer to the clinical question, in light of the evidence synthesis and other dimensions, such as health benefits or cost-effectiveness.

The evidence evaluation system developed at CCHMC is known as **LEGEND** (“Let Evidence Guide Every New Decision”) and is found on the EBDM website¹. The LEGEND system is used at CCHMC for the BEST development process, including the evidence appraisal forms, the table of evidence levels, grading a body of evidence, judging the strength of a recommendation, a glossary, and a study design algorithm.

EBDM REVIEW PROCESS

Once the document has been developed, the completed BEST is submitted for review. Two independent reviewers, trained in EBDM, evaluate the BEST against a defined set of quality criteria. A completed BEST is posted both internally ([CenterLink](#)) and externally (www.cincinnatichildrens.org/evidence or www.nqc.gov).

IMPLEMENTATION AND EVALUATION OF THE RECOMMENDATION

Implementation includes identifying how the recommendation is put into practice. Involving identified stakeholders in the implementation process will increase the likelihood of success. Implementation will be evaluated through outcome and process measures (*Conclusion: Putting Evidence into Practice*).

¹ [EBDM website – LEGEND \(CenterLink\)](#)
[EBDM website \(CCHMC\)](#)

Evidence-Based Decision Making Steps

STEP 1: DEVELOPING A CLINICAL QUESTION

Once a topic has been selected for development of a BEST, identify and refine the clinical question using the PICO format (*Patients/Population, Interventions, Comparisons, and Outcomes of interest*). Key components of the clinical question define the criteria for a more precise electronic literature search.

Components of a clinical question include the following:

P Patient / Population

Identify the condition-specific group (*Population*) for which outcome improvement is desired. Some examples of population characteristics may include but are not limited to:

- Age
- Gender
- Disease / Condition
- Care Setting

Example: Among school-aged children with candy cravings who are studying,

I Intervention

Identify specific *Intervention* that may affect the desired outcome. Intervention may be a clinical intervention or a process change.

Example: does eating peanut M&Ms

C Comparison

Identify the current clinical practice (*may be no treatment*).

- Describe current practice, if known by team, based on collective experience.
- Conduct an electronic survey of current practice, if not fully aware of current practices.
- Conduct chart reviews to determine current practice, if other methods are not sufficient.

Example: compared to plain chocolate M&Ms

O Outcome

Identify clinical or functional outcomes or results that are desired. *Outcome* is measurable.

Example: improve homework completion and/or grades?

Once all components have been identified, the clinical question can be written:

Example: Among school-aged children with candy cravings who are studying, do peanut M&Ms compared to plain chocolate M&Ms improve homework completion and/or grades?

Scope of the Clinical Question:

Consider how general or specific the clinical question is.

If the clinical question is too general, the resulting volume of literature may be high, but not necessarily appropriate.

If the clinical question is too narrow, the resulting volume may be too low or nonexistent.

To be submitted for review and posting by CCHMC (*see Review & Posting*), the BEST must be developed within the scope of care provided by or in collaboration with CCHMC.

Other versions of the PICO question include PICO(TT) or PICO(TS):

PICOTT:

Population, Interventions, Comparators, Outcomes, Timing, Type of study

PICOTS:

Population, Interventions, Comparators, Outcomes, Timing, Setting

WE HAVE THE CLINICAL QUESTION, NOW WHAT?

Once the clinical question is developed, the team asks whether the question is important and merits continuing development of a recommendation and possible BEST.

The following table may be helpful guidance for the team in this decision:

| Status of the Evidence Base and Our Knowledge and Use of it in Practice | Team Action |
|---|---|
| A. If the evidence is pretty good and we all know what it is and our practice is consistent or standardized... | Let's not spend our limited time on this question; we're doing a pretty good job with this. |
| B. If at least some of us are aware of some good evidence, but our division doesn't really have it down yet in terms of dissemination to all providers, change in practice, and standardization of care... | It could be helpful to systematically search, appraise and synthesize the evidence, so that we could distill it down into a specific and unambiguous recommendation that we could codify into practice. |
| C. If there is little to no evidence, but there is credible expert consensus (external and/or internal), and we could agree on a recommendation in order to standardize care... | It could be helpful to approve a consensus recommendation in order to standardize care. |
| D. If there is a large body of evidence, but it's not clear how much of it is good evidence and/or whether the results are consistent, and/or there is no good synthesis of this large body of evidence to easily get answers... | If there is strong interest in the topic... It could be helpful to systematically search, appraise and synthesize the evidence, so that we could distill it down into a specific and unambiguous recommendation that we could codify into practice. |
| | If there is little interest in the topic... Let's not spend our limited time with this question at this point in the process. |
| E. If there is no evidence and there's a lack of consensus... | With no recommendation to implement, consider research or dissemination of the need for research in this area. |

Proceed to Step 2: Conducting the Literature Search

Refer to the EBDM website for additional information related to this step and other EBDM resources:

[CCHMC employees](#)

[Users not employed by CCHMC](#)

STEP 2: CONDUCTING A LITERATURE SEARCH

Additional resources for conducting the literature search may be accessed on the EBDM website² or via the Edward L. Pratt Research Library, such as personnel, software, databases, or educational workshops.

A. Identify the criteria *a priori* for considering studies for the evidence review

In order to establish the *a priori* criteria, some investigation into what evidence is available is merited.

1. Types of Studies
Study designs being considered for inclusion in the systematic review
2. Types of Participants
Patients/Population(s) which were considered for inclusion in the systematic review
(*What populations were applicable to this review? For example, only pediatric studies were planned for inclusion.*)
3. Types of Interventions
Interventions and Comparisons which were considered for inclusion in the systematic review
4. Types of Outcomes
Outcomes which were considered for inclusion in the systematic review
5. Exclusion Criteria, if any
Additional criteria for exclusion that go beyond simply the opposite of the inclusion criteria

B. Using the criteria above and the clinical question(s) developed in Step 1,

Identify search terms that may be helpful in conducting the electronic literature search, including the following:

1. Keywords or MeSH Headings
Use the patient population and/or intervention as keywords to begin the search
(*i.e., Medical Subject Headings; e.g., patient population, setting, intervention.*)
2. Limits, Filters, and Search Date Parameters
Limits and/or filters (*e.g., English language, publication dates, ages, etc.*) may assist in focusing the search results.

C. Perform electronic literature searches using search terms identified above.

(*Appendix 4 Beyond the Basics Search Techniques, Appendix 5 Constructing a Search Strategy, Appendix 6 Literature Search Algorithm*)

1. Databases used for search may include, but are not limited to:
 - a. MedLine (*Search engines for MedLine include OVID or PubMed*)
 - b. CINAHL
 - c. *The Cochrane Library* / Cochrane Database for Systematic Reviews
 - d. PsychInfo
2. Relevant CCHMC Evidence-Based Documents should be considered for inclusion in the Evidence Synthesis
(*Body of Evidence*).

Available CCHMC resources include [Evidence-Based Care Recommendations](#)
Evidence-Based Care Guidelines & Best Evidence Statements (BEST) – www.cincinnatichildrens.org/evidence

² [CCHMC employees](#)
[Users not employed by CCHMC](#)

3. Clinical Practice Guidelines may also be found on association websites or other sites, including the [National Guideline Clearinghouse](#).
4. Search results may be exported/imported into electronic reference manager, such as EndNote or RefWorks.

For additional help with this item or institutional access to EndNote or RefWorks, if you are a CCHMC employee, refer to these resources from Pratt Library: [EndNote](#) or [RefWorks](#)

D. Document the Search Strategy on the BEST template in the appendix (*Appendix: Evidence Search Strategy, Results, & Evidence Table*), once you know you have the correct searches completed, including the following:

1. Database(s)
2. Search Terms
3. Limits, Filters, and Search Date Parameters
4. Date of Most Recent Search
5. Any solicitation of information from ListSers or other personal correspondence/communication
6. Search results from organizations that provide secondary syntheses
(*e.g., Clinical Evidence, Up-To-Date*)
7. Reference list searches
(*e.g., hand-searching of reference lists from related articles*)
8. Relevant CCHMC Evidence-Based Documents
(*e.g., Evidence-Based Guidelines, Best Evidence Statements/BEST*)

If CCHMC guidelines or BESTs are found and are applicable to this BEST, include in the Discussion/Synthesis of the Evidence and include the citation in reference list.

E. Reduce search results by discarding duplicates and applying the *a priori* inclusion/exclusion criteria (*defined in section A above*). Based on the titles and/or abstracts:

1. Discard search results that obviously do not satisfy the *a priori* criteria for inclusion and any results that meet the exclusion criteria
2. Retain search results that may meet inclusion criteria

F. Retrieve full text of articles retained based upon title/abstract review above (*E*).

G. Apply *a priori* inclusion criteria to full text review of articles retaining only those articles that meet the inclusion criteria.

H. Document the Search Results & Methods in the appendix of the BEST
(*Appendix: Evidence Search Strategy, Results, & Evidence Table*)

1. Required documentation
 - a. Total number of articles *identified* in database searches and other sources (*See C above*)
 - b. Total number of articles meeting the inclusion criteria
The final number of articles meeting inclusion criteria may be determined after critical appraisal (see Steps 3–4).

2. Optional documentation

- a. Number of articles identified from electronic databases
- b. Number of articles identified from reference lists or hand searches
- c. Number of articles discarded or excluded
 - Reasons for discarding:
 - duplicates (*n=#*)
 - does not meet inclusion criteria (*n=#*) or met exclusion criteria (*n=#*)
 - other reasons not identified here
- d. Number of articles reviewed in full text and critically appraised

WE HAVE THE EVIDENCE SEARCH RESULTS, NOW WHAT?

Once the evidence has been found to meet inclusion criteria for the review, the team continues with critical appraisal of the evidence.

| | | |
|--|--|---|
| For clinical questions with sufficient evidence to make a recommendation: | | <p>Proceed to Step 3:</p> <p>Critically Appraising the Individual Studies / Articles</p> |
| For clinical questions with <i>insufficient</i> evidence to make a recommendation: | The team may want to work on developing a recommendation based on consensus | <p>Proceed to Step 5: Developing a Care Recommendation</p> <p>See Step 5. B. 4. Writing Consensus-Based Recommendations</p> |
| | The team may want to suggest further research, if the team is unable to work on developing consensus | |

Refer to the EBDM website for additional information related to this step and other EBDM resources:

[CCHMC employees](#)

[Users not employed by CCHMC](#)

STEP 3: APPRAISING AND COMPILING RESULTS OF THE INDIVIDUAL STUDIES / ARTICLES

Evaluation of the evidence includes critically appraising each study you selected as applicable to your clinical question in step 2.

A. Determine the domain of the clinical question¹:

Which of the following domains does your PICO/clinical question address?

1. Therapy / Treatment / Prevention / Harm
2. Diagnosis / Assessment
3. Prognosis
4. Meaning / Knowledge, Attitudes, Beliefs (KAB)
5. Etiology / Risk Factors
6. Prevalence / Incidence
7. Cost-Analysis / Decision-Analysis

B. For each individual study/article:

1. Determine the study design³
2. Choose the relevant Evidence Appraisal Form⁴
3. Read each individual article:
Use the questions in the top section of the evidence appraisal form as a guide to continue with critical appraisal for each individual article.
 - a. Verify that each study helps to answer the clinical question.
 - b. If individual studies do not help to answer the clinical question, then critical appraisal of those studies is discontinued.
4. Complete evidence appraisal form for all individual studies that help to answer the clinical question.
 - a. Comment fields may be used to highlight methods, results, or conclusions to help with synthesizing the evidence and developing care recommendations in later steps.
 - b. Consider how the individual study contributes to the answer for the clinical question and use the "Additional Comments" field to document your conclusions.
 - c. These conclusions may be used in later steps of synthesizing the evidence and/or developing the care recommendation statement.
5. Assign the Evidence Level⁵ (*abbreviated table at the end of each evidence appraisal form*)

C. Compiling results for comparison of the individual articles

1. The purpose is to have all individual article information meeting the inclusion criteria in one place for comparison of all articles to each other.
2. The columns of an evidence table may include, but are not limited to:
 - a. Population (*e.g., Patients, Setting, Sample/Sample Size*)
 - b. Intervention / Comparison
 - c. Outcomes
 - d. Results
 - e. Conclusions
 - f. Evidence Level

³ LEGEND – [Evaluating the Evidence Algorithm](#)

⁴ LEGEND – [Evidence Appraisal Forms Table](#)

⁵ LEGEND – [Table of Evidence Levels](#)

3. Extract information from each article and add it into the Evidence Table.
4. The Evidence Table of Included Studies is documented on the BEST template in the appendix.
(*Appendix: Evidence Search Strategy, Results, and Evidence Table of Included Studies*)

WE HAVE THE EVIDENCE APPRAISED, NOW WHAT?

Once the individual studies / articles are appraised, the team synthesizes this evidence.

The evidence synthesis includes articles meeting the inclusion criteria and how they influence the recommendation(s).

Proceed to Step 4: Synthesizing the Evidence

Refer to the EBDM website for additional information related to this step and other EBDM resources:

[CCHMC employees](#)

[Users not employed by CCHMC](#)

STEP 4: SYNTHESIZING THE EVIDENCE

Individual, appraised studies/articles (*with assigned Evidence Levels*) are now compiled into an evidence summary describing how the studies relate to the clinical question.

- A.** The purpose is to synthesize evidence from the evidence table to concisely answer the clinical question.
1. What does the evidence tell you about the clinical question?
 - a. Based on the evidence summary above of articles related to the clinical question, discuss themes, concepts, commonalities/similarities, differences, or evidentiary gaps from the articles reviewed and appraised.
 - b. This synthesis is not a narrative of each article, as in the evidence summary section above, but a synthesis of the articles combined forming the “Body of Evidence.”
 2. How does the evidence inform the clinical question?
- B.** The evidence synthesis is documented on the BEST Template as the “Discussion / Synthesis of the Evidence related to the recommendation(s)”
1. The evidence synthesis of the Body of Evidence is used to develop a care recommendation for the clinical question.
 2. References are cited in the text of the discussion/synthesis with the evidence level included.
 3. A description of the quality (*including applicability*), quantity (*including completeness*), and consistency of the aggregate available evidence. (*See Step 5: Grade for the Body of Evidence*)
 4. A description and explanation of any differences of opinion regarding the recommendation.

WE HAVE THE EVIDENCE SYNTHESIS AND EVIDENCE TABLE, NOW WHAT?

When the evidence has been summarized and synthesized, the team proceeds to the next step to develop a recommendation.

Proceed to Step 5: Developing a Care Recommendation

Refer to the EBDM website for additional information related to this step and other EBDM resources:

[CCHMC employees](#)

[Users not employed by CCHMC](#)

STEP 5: DEVELOPING A CARE RECOMMENDATION

The care recommendation is developed explicitly with the supporting evidence and other dimensions (*below*), demonstrating how the body of evidence answers the clinical question. Consider the target population in developing the care recommendation.

A. Identify Target Population for the BEST

- The population (*e.g., patients, public*) to whom the recommendation is meant to apply is specifically described. This includes defining any inclusion or exclusion criteria for the population to which the recommendation statement applies (*e.g., age group, presence/absence of comorbidities, care setting*).

B. Write the Care Recommendation Statement

- To be easily identifiable, the recommendation will begin with one of the following phrases reflecting the strength of the recommendation (*based on the dimensions listed in item C below*):

- It is recommended that ...
It is recommended that ...not...
- It is strongly recommended that ...
It is strongly recommended that ...not...

In order to designate 'strongly recommended,' review and documentation of the Dimensions are required – see Section C below.

- There is insufficient evidence and a lack of consensus to make a recommendation on...
Review and document the rationale for the decision of "insufficient evidence and a lack of consensus."

Consider the Dimensions (*See section below C. Judge the Strength of the Recommendation*) in development of the recommendation statement.

- To be specific and unambiguous, the recommendation will include an action verb and state:

- Who are being addressed (*e.g., which patients / caregivers*)
- What is being recommended (*e.g., which specific treatment, test, or prognostic marker*)
- When
- Where (*e.g., in course of disease/location – home, clinic, ED, hospital bed, ICU*)

- Document citations for the recommendation at the end of the statement:

- Examples of formatting citations include:
 - Primary Author, Year, [Evidence Level] (*e.g., (LastName Year [3b])*)
 - Local Consensus, [Evidence Level] (*i.e., (Local Consensus [5])*)
 - APA (*American Psychological Association*) formatted citation **PLUS** [Evidence Level] (*e.g., (APA formatted citation [4a])*)
- One effective way to present citations is to order them by **(1)** evidence quality level, **(2)** year of publication, then **(3)** alphabetical by first author. This order presents cited evidence of the highest quality level first and then in order of year and author. If quality levels are low or equal, citations are in order of year and author.
- If using bibliography software to manage citations, such as EndNote or RefWorks, the reference list will be completed as citations are added to the BEST Template. *If not*, enter references manually, alphabetically by first author, into the References section of the BEST Template.
- All citations used in the BEST are included in the References.

4. To develop recommendations based on local consensus:
 - a. Local consensus is pursued if the evidence, or lack thereof, falls into one of these categories:
 1. Published, appraised articles give inconsistent results
 2. Published, appraised articles are not valid, reliable, or applicable for answering the question
 3. Insufficient or no evidence was found related to the clinical question
 - b. Identify all disciplines that may have an impact or effect on the care recommendation.
 - c. Identify potentially supporting or opposing viewpoints about what recommendation to make.
 - d. Draft a recommendation statement to begin the consensus process.
 - e. Elicit input on draft statement from all representing groups, divisions, or disciplines and provide feedback to the development team.
 - f. Attempt to come to an agreement regarding a recommendation statement.
 1. If agreement is reached and appropriate viewpoints were considered, a consensus recommendation is finalized:
"It is recommended that ..." or
"It is recommended that ...not..."
 2. If the team agrees that there is insufficient evidence and lack of consensus to make a care recommendation, then the statement is:
"There is insufficient evidence and lack of consensus to answer the clinical question or make a care recommendation."
 3. For a formal consensus process, helpful techniques may include Nominal Group Process or Delphi Technique.
 - g. Describe the consensus process in the section for Discussion/Synthesis of the Evidence.
5. Notes *(as appropriate)*
 - a. A Note follows and is associated with a recommendation.
 - b. A Note is sometimes used to:
 1. discuss specific evidence related to the recommendation
(e.g., number needed to treat (NNT), data clarifying the recommendation)
 2. emphasize key points/issues related to the recommendation
(e.g., safety, harm, applicability, dimensions for judging the strength of a recommendation)
 3. mention exceptions to the recommendation
 - c. References for the notes are cited at the end of the note, as appropriate.
6. Additional Recommendation Statements
 - a. For some clinical questions, multiple recommendations may develop from the synthesized evidence. This evidence would help to answer the clinical question, but may cover multiple outcomes and, thus, multiple recommendations.
 - b. If more than one recommendation statement results from one clinical question, repeat Step 5 *(B. 1 to 5)* for each recommendation statement.

C. Judge the Strength of the Recommendation Statement

To judge the strength of the recommendation, consider the following dimensions⁶:

1. Body of Evidence (BOE)

- a.** Individual studies combine to form the BOE (*i.e.*, *the evidence synthesis*) and are used in development of the care recommendation, based upon the synthesis of the evidence.
- b.** The BOE addresses the clinical question and is relevant to the recommendation statement.
- c.** Grading allows consideration of the quality, quantity, or consistency of the BOE
 - 1.** Quantity: the aggregate of quality ratings for individual studies
 - 2.** Quality: the magnitude of the effect or the numbers of studies
 - 3.** Consistency: the extent to which similar findings are reported using similar and different study designs
- d.** Grades of high, moderate, low, or grade-not-assignable⁷ are used to describe the quality of the body of evidence. (*A more detailed grade description is provided online – see footnote²*)
 - 1.** High:
 - i.** Sufficient number of high-quality studies with consistent results
 - ii.** Further research is unlikely to change our confidence in the answer to the clinical question
 - 2.** Moderate:
 - i.** Multiple studies of lesser quality or with inconsistent results OR a single well-done study
 - ii.** Further research is likely to have an important impact on our confidence in the precision of the answer to the clinical question, and may even change the answer itself
 - 3.** Low:
 - i.** Expert opinion, case reports, case studies and general reviews
 - ii.** There is local and/or published consensus, but no research, to answer the clinical question
 - iii.** Further research is very likely to have an important impact on the answer
 - 4.** Grade-not-assignable:
 - i.** Insufficient design or execution, too few studies, and inconsistent results
 - ii.** There is insufficient evidence and lack of consensus to answer the clinical question
 - iii.** Document “Grade Not Assignable” in the Rationale for the BOE in the dimensions table and leave the boxes unchecked.
- e.** If the studies are not easily categorized by quantity, quality and consistency, additional concepts on the LEGEND tool for [Grading the BOE](#) are provided to guide the user in determining the grade for the body of evidence.
- f.** Using evaluation criteria for determining the BOE grade increases user confidence in the resulting recommendation.

⁶ LEGEND – [Judging the Strength of a Recommendation](#)

⁷ LEGEND – [Grade for the Body of Evidence](#)

2. Safety / Harm

Identify any potential adverse effect(s) for the safety or harm of the patient population, if the recommendation is implemented.

- a. Minimal adverse effects
- b. Moderate adverse effects
- c. Serious adverse effects

3. Health benefit to patient

Identify any potential health benefit(s) for the patient population, if the recommendation is implemented.

- a. Significant health benefit
- b. Moderate health benefit
- c. Minimal health benefit

4. Burden on patient to adhere to recommendation

Identify the potential burden of adherence for the patient population
(e.g., cost, hassle, discomfort, pain, motivation, ability to adhere, time)

- a. Low burden of adherence
- b. Unable to determine burden of adherence
- c. High burden of adherence

5. Economic impact to healthcare system

Identify the economic impact to the system, if the recommendation is implemented
(e.g., balance of cost/savings of resources, staff time, and supplies based on published studies or onsite analysis)

- a. Cost-effective to healthcare system
- b. Inconclusive economic effects
- c. Not cost-effective to healthcare system

6. Directness

Identify the directness to which the BOE directly answers the clinical question (PICO)

- a. Evidence directly relates to the recommendation for this target population
- b. There is some concern about the directness of the evidence as it relates to the recommendation for this target population
- c. Evidence only indirectly relates to the recommendation for this target population

7. Impact on morbidity/mortality or quality of life

Identify the potential impact on morbidity / mortality or quality of life, if the recommendation is implemented.

- a. High impact on morbidity/mortality or quality of life
- b. Medium impact on morbidity/mortality or quality of life
- c. Low impact on morbidity/mortality or quality of life

- D.** Complete your dimension review in the table under the Discussion / Synthesis of Evidence related to the recommendation(s). When applicable, provide rationale on the BEST for judgment and selection of the dimensions below including citations.

WE HAVE THE RECOMMENDATION(S) WRITTEN, NOW WHAT?

- A.** Confirm that the BOE and Recommendation address the Clinical Question.
- B.** Consider if the BOE and Recommendation are compelling enough to make a change and to dedicate resources.

Proceed to Putting Evidence Into Practice

Refer to the EBDM website for additional information related to this step and other EBDM resources:

[CCHMC employees](#)

[Users not employed by CCHMC](#)

Conclusion

Putting Evidence into Practice

Once the BOE is determined and the recommendation is developed, you now need to explore whether these are compelling enough to implement. You need to weigh the resources and effort needed for implementation against the outcome implementation will produce. Considerations regarding the proposed practice change and resources may need to be re-discussed with primary stakeholders.

Rationale for pursuing implementation of the BEST recommendation may include:

- Implementation of the recommendation provides an opportunity to improve the desired outcome(s) or to decrease variation in practice.
- The strength of the recommendation influences support for a change.
- Evidence indicates a need for change.
(e.g., outcomes for patients, staff, or organization; implementation of new practice or technology; incorporation of innovation; standardizing practice)
- Potential benefits of practice change merit short- and long- term costs and investment of resources.
(e.g., efficient and fiscally responsible use of resources, cost-effectiveness)
- Recommendation and evidence remain consistent with priorities established when the project was approved and/or throughout development of the BEST.
(e.g., supports current strategic initiatives, unit level resources commitment)
- Implementation of the recommendation may improve safety and will not cause harm.
- Barriers can be identified and mitigated to sustain the practice change.

Based on your decision for implementation, complete the **Implementation** section on the BEST:

A. Applicability & Feasibility Issues *(see example below)*

1. This section briefly describes items that may positively or negatively impact the successful implementation of this recommendation such as:
 - a. Define potential facilitators and barriers within the practice setting that may help or hinder the implementation
(Facilitators – e.g., leadership support, strong evidence)
(Barriers – e.g., systems not in place, resources not available, baseline data not available, not currently an organizational priority, unfamiliarity with the quality improvement process)
 - b. Determine potential resource needs
(e.g., cost, equipment availability, appropriate staff availability)
 - c. Identify tools or processes which need to be developed, adapted, or revised for incorporation of the recommendation into practice
(e.g., clinical pathways, order sets, EPIC/EMR, family education materials, Knowing Notes, Health Topics)
(See Relevant CCHMC Tools for Implementation below)
2. If no recommendation is made *(e.g., insufficient evidence)*, include a statement such as, “This team did not consider applicability issues, due to no recommendation being developed.”

B. Relevant CCHMC Tools

Available CCHMC resources (www.cincinnatichildrens.org) which may need to be updated include:

- a. Internal policies and procedures
- b. Knowing Notes or Health Topics
If available, copy and paste the www.cincinnatichildrens.org web address for these items into the BEST.
- c. If there are no existing tools for implementation, including a statement such as, "No CCHMC Tools for Implementation were found."

C. Outcome Measures and Process Measures

1. This section briefly describes the desired outcomes resulting from implementation of the recommendation and how they are measured including:
 - a. Identify specific outcomes and related processes addressed in the recommendation and affected by implementation of the recommendation.
 - i. Consider outcomes used in the evidence for the recommendation
(Cite if applicable)
 - ii. Current/baseline data may be reported in this section, if available.
 - b. Think about the rationale for measuring these outcomes or processes.
 - i. Why are you measuring the outcome/process?
 - ii. What are you trying to change?
 - iii. How would you measure the outcome/process?
 - iv. How will you know you have improved the outcome/process?
 - c. Write the outcome measures and process measures along with the rationale on the BEST.
(See example below)
 - i. Identify measures that could be used to evaluate the outcomes and processes affected by implementation of the recommendation.
 1. Process measures evaluate the way care is provided. These may include technical (*e.g., procedures, therapies, wait time, cost*) or interpersonal (*e.g., communication, compassion*) processes.⁸
 2. Outcome measures (*e.g., patient satisfaction, health status, illness, injury, rehospitalization, morbidity, mortality, incidence, prevalence*) evaluate the effectiveness of processes that constitute health care delivery.¹
 3. Consider work flow when choosing outcome measures and process measures to not over-burden clinicians.
(If outcome assessment requires additional monitoring beyond what is already captured in normal work processes, consider using tools that have already been validated to monitor those outcomes, if available.)
 - ii. Include a rationale for choice of each measure (*i.e., outcome and process*).
2. If no recommendation is made (*e.g., insufficient evidence*), include a statement such as, "This team did not consider outcome or process measures, due to no recommendation being developed."

⁸ Singh, D. (2012). *Delivering health care in America: A systems approach* (5th ed.) Burlington, MA: Jones and Bartlett.

| |
|---|
| EXAMPLE |
| <p>Clinical Question: Among school-aged children with candy cravings who are studying, do peanut M&Ms compared to plain chocolate M&Ms improve homework completion and/or grades?</p> |
| <p>Recommendation Statement: It is recommended that a single serving of peanut M&Ms be provided to school-aged children during homework sessions to enhance homework completion and increase grade point average (GPA) (<i>Hershey 2010 [1a], Charlie 2008 [2a], Chocolate Factory 2009 [2a]</i>). NOTE: When using M&Ms as a study tool, increasing exercise is encouraged to counteract any concerns for weight gain (<i>Lelane 1990 [3a], Fonda 1988 [4b], Simmons 2001 [4b]</i>). NOTE: Effect sizes with plain chocolate M&Ms were small and did not approach significance. However, a similar trend to peanut M&Ms was noted (<i>Chocolate Factory 2009 [2a]</i>).</p> |
| <p>Applicability Statement: Availability of M&Ms may vary by household and budget. Additionally, implementation may be affected by the child's desire or time to adhere to homework sessions. Consider allergies in the implementation of this recommendation.</p> |
| <p>Outcome Measure Statement: For school-aged children, homework completion will be at 90% and GPA will improve by 0.5 points in three months.</p> |
| <p>Process Measure Statement: Peanut M&Ms will be included on the weekly household grocery list. During homework sessions, children will receive one serving of peanut M&Ms. Homework completion will be monitored weekly. Grades (GPA) will be monitored quarterly.</p> |

RESOURCES AT CCHMC FOR IMPLEMENTATION OF AN EVIDENCE-BASED CARE RECOMMENDATION

CCHMC tools are available: [Quality Improvement Tools \(e.g., AIM, KDD, PDSA\)](#)
[Other Resources \(e.g., team charter\)](#)

At CCHMC, consultation may be available for strategic initiatives. For needed improvement guidance, contact Clinical Outcomes Managers or Quality Improvement Coordinators (QIC).

Completing the Supporting Information

All steps to develop an evidence-based care recommendation are done. Remaining items need to be added to complete the BEST, including the Supporting Information section. Continued use of the User Checklist will guide you through the completion of the BEST. The BEST Template, User Checklist, & Reviewer Checklist (*Appendix 1, Appendix 2, Appendix 8*) are adapted from internationally recognized criteria ([AGREE: Appraisal of Guidelines for Research & Evaluation](#)).

A. Title

- A good title (*typically less than 12 words long*) will use descriptive terms and phrases that accurately highlight the core content of the BEST, including all key words and avoiding non-essential words and word repetition.

B. Reference List

- Check all references and citations for evidence levels, formatting, and consistency.
- If using bibliography software to manage citations, such as EndNote or RefWorks, the reference list will be completed as citations are added to the BEST Template.

If not, enter references manually, alphabetically by first author, into the References section of the BEST Template.

C. Background / Purpose of BEST Development

Background or purpose information includes your rationale for choosing the topic. These questions may help in developing your rationale:

1. Why was this BEST developed?
2. Why is this topic important?
3. Is this connected to a strategic initiative or other organizational priority?
4. What needs or issues encouraged pursuing a recommendation for your topic?
5. Who is the target user of the BEST?
(*e.g., specialty, discipline, primary care, parent, etc.*)
6. What brought you to this clinical question now?

D. Definitions

1. Definitions may be useful to provide:
 - a. Additional information for the target users
 - b. Specialty-specific terms, if appropriate
2. Definitions may be developed based on provider knowledge of the topic or evidence derived from the BEST development process.
In the latter case, if citations are used to support definitions, provide an evidence level with the accompanying citation(s).
3. If you choose not to complete this section, then the header can be deleted from the template.

E. Group/Team Members

List members (*including Name, Credentials, Specialty/Area of Expertise*) who participated in the BEST development or content review, such as:

Multidisciplinary Team

1. Team Leader/Author
2. Team Members/Co-Authors
3. Patient/Family/Parent or Other Parent Organization *(e.g., Family Advisory Council)*

Other BEST Development Support

4. Ad Hoc Advisors/Content Reviewers *(e.g., internal expert review)*
5. Support Personnel/Consultants

F. Known Conflicts of Interest (Col)

Indicate financial or intellectual conflicts of interest (*Appendix 9*)

1. Group / Team members (*multidisciplinary team and content reviewers/ consultants*) complete and sign Col forms
2. Check the appropriate boxes and complete stated conflicts, if any:
 - a. "No financial or intellectual conflicts of interest were found."
 - b. "{State found conflicts.}"
3. Col forms are submitted with the BEST and archived with the BEST.

Refer to the EBDM website for additional information related to this step and other EBDM resources:

[CCHMC employees](#)

[Users not employed by CCHMC](#)

Reviewing and Posting the BEST

A. User Review & the User Checklist

1. Review your BEST, using established criteria included in the User Checklist (*Appendix 2*).
2. Peer, consultant, or other stakeholder review (*e.g., EBP mentor, Anderson Center consultant, support personnel*) of the BEST prior to submission is recommended. List those who give feedback as Content Reviewers.
3. Verify format and style are consistent and professional throughout the BEST, including but not limited to:
 - a. Conducting spell check on the document text
 - b. Defining acronyms the first time used in text
 - c. Numbering tables, figures, and appendices in the order of appearance in text
 - d. Assuring that journal names are consistently used in the references (*e.g., use either the full name or the abbreviation for all references*)
 - e. Choose a consistent reference style for all citations in the text and all references in the reference list (*e.g., APA formatted citation or EBDM format (i.e., AuthorLastName Year) PLUS Evidence Level (i.e., [#a/b])*)
4. Submit your BEST for Evidence Collaboration Review to EBDMinfo@cchmc.org.

B. Evidence Collaboration Review Process & the Reviewer Checklist

1. The BEST will be reviewed by two independent Evidence Collaboration Reviewers, using established criteria included in the Reviewer Checklist (*Appendix 8*).
2. Reviewers commonly suggest improvements to the BEST draft. Some changes are required to pass the review process.
3. Team members are expected to remain engaged during this process to assist with any revisions. The review process may require multiple iterations of revision.
4. If changes are **not** made based on reviewer comments/suggestions, please respond with how those comments/suggestions were considered (*e.g., using Comments or other means*)
5. Failure to meet established criteria may result in rejection of the BEST. These two conditions would need to be met in order for a BEST to be rejected:
 - a. One or more of the following three circumstances is true:
 - Author has not demonstrated substantial improvement toward meeting checklist criteria.
 - BEST has failed fourth review (*i.e. the reviewers are seeing the document for the fourth time*).
Warning was provided at third review that substantial improvement must be made.
 - Six months since latest submission

AND

- b. Combined agreement of the reviewers as to whether there is good reason to reject, instead of working toward a final product.

Authors may decide at any point in the review process to withdraw the BEST from consideration for approval.

6. Once the review process is completed, the Team Leader will be notified that the BEST is approved.

C. External Review Process (*Future process to be added*)

D. Posting Process

1. The Evidence Collaboration's Information and Knowledge Management group will categorize the BEST, once approved for posting (*i.e., topic, discipline/specialty, and type of guidance*).
2. Authors will be provided with a final page proof of the BEST to review prior to posting.
3. The BEST is posted on:
 - a. [Cincinnati Children's website](http://www.cincinnatichildrens.org/evidence) (www.cincinnatichildrens.org/evidence)
 - b. Agency for Healthcare Research and Quality (AHRQ)
– [National Guideline Clearinghouse](http://www.ngc.gov) (NGC - www.ngc.gov)
(*The NGC may not accept BESTs without a clinical focus.*)

Refer to the EBDM website for additional information related to this step and other EBDM resources:

[CCHMC employees](#)

[Users not employed by CCHMC](#)

Maintaining the Body of Evidence & Revising the BEST

Peer-reviewed literature should be monitored regularly to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the BEST. If a BEST is not revised at the end of **five years** from the date of posting, it will expire and be removed from all sites (*Refer to posting section*).

The team leader is responsible for maintaining the body of evidence and keeping the BEST up-to-date. A BEST may be revised at any time, if the team finds new evidence. Revising a BEST follows the same process as BEST development, including review and posting of the BEST. When revising a BEST, always use the newest template ([CenterLink EBDM](#)).

A. Ongoing Literature Search and Review

1. Searching for new evidence related to the BEST may occur on a regular basis.
 - a. Frequency of searches may be determined by the:
 - i. volume of new articles published related to the clinical question/topic
 - ii. amount of time available to review new evidence
 - iii. available team members to “share” the evidence review process
 - b. The evidence review may be triggered by a seminal study.
 - c. Automatic searches may also be set up in the search engines (*e.g., Ovid, PubMed, EBSCO*) to send notification of newly published articles related to the clinical question via email or RSS feed (*Really Simple Syndication*).
Help sections of search engines provide direction in setting up automatic searches.
If you are a CCHMC employee, the Edward L. Pratt Research Library may provide additional help with this item.
2. Review titles and abstracts in the search results for references that are relevant to the clinical question
(*See the EBDM Step 2 section*)
3. If **NO** new evidence found:
 - a. Update the following in the BEST and resubmit:
 - i. Search Date Parameters and Date of Most Recent Search in the Search Strategy table of the Appendix
 - ii. Review History table ([see B. Review History below](#))
 - b. If searches are more frequent with no new evidence, updates may be submitted annually.
 - c. The BEST would be reposted following a Publication Review Process.
4. If new evidence is found and related to the clinical question/topic:
 - a. Repeat the evidence evaluation process (*Repeat Steps 3 through 5*)
 - b. Determine action, if any, related to the recommendation(s) and BEST
 - i. Does the evidence support the recommendation?
If so, add references, update the discussion/synthesis with the new evidence, and update the search strategy, results, and evidence table in the appendix.
 - ii. Is there invalidating evidence that would change the recommendation?
If so, revise the recommendation statement and revise the BEST.

B. Review History

Once a BEST is complete, the original publication date is included in the BEST Review History table at the end of the BEST by the author. An ongoing evidence review is necessary to maintain currency of evidence and the recommendation statement(s). Review history events are inserted as a new row in the table, ordering them with the most recent event as the top row. Each entry provides publication dates, events, and outcomes of the events.

If there are changes to the clinical question, then a new BEST should be developed.

Review history events include:

1. Original Publication

- a. The first publication date of the BEST will be included in the Review History table. For the original BEST, this date will match the date on the first page of the BEST and be the only entry in the table.
- b. The Outcome would be described as – New BEST developed and published.

2. Subsequent Events**a. Literature Search**

Outcomes

- i. No new evidence found.
- ii. New evidence with no recommendation change.
- iii. New evidence with recommendation change.

b. Amendment *(Edits not as a result of a literature search)*

Outcomes

- i. Health topic or other implementation tool added.
- ii. Format changes made.
- iii. Outcome Measures changed *(and/or)* Process Measures changed.
- iv. New team members added.
- v. Other changes not altering the recommendation or evidence.
(Please provide description)

C. Reviewing and Posting a Revised BEST *(BEST Manual: Conclusion – Reviewing and Posting the BEST)*

1. If new evidence was found and changes were made to the recommendation, then the revised BEST will be submitted for Checklist Review.
2. If new evidence was found and changes were not made to the recommendation, then the revised BEST will be submitted for Checklist Review.
3. If no new evidence was found, then the revised BEST will be submitted for Publication Review.

Refer to the EBDM website for additional information related to this and other EBDM resources:

[CCHMC employees](#)

[Users not employed by CCHMC](#)

Title

Clinical Question (in PICO format)

| | | |
|---|----------------------|--|
| P | (Population/Problem) | |
| I | (Intervention) | |
| C | (Comparison) | |
| O | (Outcome) | |
| | | |

*Definitions for terms marked with * may be found in the Supporting Information section.*

Target Population for the Recommendation (Inclusion / Exclusion Criteria for the recommendation)

Recommendation(s)

Notes: (Optional)

Discussion / Synthesis of Evidence related to the recommendation(s) – See Appendix for the Evidence Table of Included Studies

In determining the strength of the recommendation, the development group made a considered judgment in a consensus process which was reflective of critically appraised evidence, clinical experience, and these dimensions:

Given the dimensions below and that more answers to the left of the scales indicate support for a stronger recommendation, the recommendation statement above reflect the strength of the recommendation as judged by the development group. (Note that for negative recommendations, the left/right logic may be reversed for one or more dimensions.)

| | | | |
|---|---|---|---|
| 1. Grade of the Body of Evidence | <input type="checkbox"/> High | <input type="checkbox"/> Moderate | <input type="checkbox"/> Low |
| <i>Rationale:</i> | | | |
| 2. Safety / Harm (Side Effects and Risks) | <input type="checkbox"/> Minimal | <input type="checkbox"/> Moderate | <input type="checkbox"/> Serious |
| <i>Rationale:</i> | | | |
| 3. Health benefit to patient | <input type="checkbox"/> Significant | <input type="checkbox"/> Moderate | <input type="checkbox"/> Minimal |
| <i>Rationale:</i> | | | |
| 4. Burden to adhere to recommendation | <input type="checkbox"/> Low | <input type="checkbox"/> Unable to determine | <input type="checkbox"/> High |
| <i>Rationale:</i> | | | |
| 5. Cost-effectiveness to healthcare system | <input type="checkbox"/> Cost-effective | <input type="checkbox"/> Inconclusive | <input type="checkbox"/> Not cost-effective |
| <i>Rationale:</i> | | | |
| 6. Directness of the evidence for this target population | <input type="checkbox"/> Directly relates | <input type="checkbox"/> Some concern of directness | <input type="checkbox"/> Indirectly relates |
| <i>Rationale:</i> | | | |
| 7. Impact on morbidity/mortality or quality of life | <input type="checkbox"/> High | <input type="checkbox"/> Medium | <input type="checkbox"/> Low |
| <i>Rationale:</i> | | | |

IMPLEMENTATION

Applicability & Feasibility Issues

Relevant CCHMC Tools

Policies, Procedures, Knowing Notes, or Health Topics OR None were found.

Outcome Measures and Process Measures

SUPPORTING INFORMATION

Background / Purpose of BEST Development

Definitions

Search Strategy & Evidence Table – See Appendix

Group / Team Members *(Name, Credentials, Specialty/Area of Expertise)*

Multidisciplinary Team

Team Leader/Author:

Team Members/Co-Authors:

Patient/Family/Parent or Other Parent Organization:

Other BEST Development Support

Content Reviewers:

Support/Consultants:

Conflicts of Interest were declared for each team member and:

- No financial or intellectual conflicts of interest were found.
- The following conflicts of interest were disclosed:

Note: Full tables of the [LEGEND evidence evaluation system](#) are available in separate documents:

- [Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality](#) (abbreviated table below)
- [Grading a Body of Evidence to Answer a Clinical Question](#)
- [Judging the Strength of a Recommendation](#) (dimensions table below and Rationale)

Table of Evidence Levels *(see note above):*

| Quality level | Definition |
|----------------------|---|
| 1a† or 1b† | Systematic review, meta-analysis, or meta-synthesis of multiple studies |
| 2a or 2b | Best study design for domain |
| 3a or 3b | Fair study design for domain |
| 4a or 4b | Weak study design for domain |
| 5a or 5b | General review, expert opinion, case report, consensus report, or guideline |
| 5 | Local Consensus |

†a = good quality study; b = lesser quality study

Table of Language and Definitions for Recommendation Strength (see note above):

| Language for Strength | Definition |
|--|--|
| It is strongly recommended that... It is strongly recommended that... not... | When the dimensions for judging the strength of the evidence are applied, there is high support that benefits clearly outweigh risks and burdens. (or visa-versa for negative recommendations) |
| It is recommended that... It is recommended that... not... | When the dimensions for judging the strength of the evidence are applied, there is moderate support that benefits are closely balanced with risks and burdens. |
| There is insufficient evidence and a lack of consensus to make a recommendation... | |

Copies of this Best Evidence Statement (BEST) and related tools (if applicable, e.g., screening tools, algorithms, etc.) are available online and may be distributed by any organization for the global purpose of improving child health outcomes.

Website address: <http://www.cincinnatichildrens.org/service/j/anderson-center/evidence-based-care/bests/>

Examples of approved uses of the BEST include the following:

- Copies may be provided to anyone involved in the organization’s process for developing and implementing evidence based care;
- Hyperlinks to the CCHMC website may be placed on the organization’s website;
- The BEST may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and
- Copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at EBDMinfo@cchmc.org for any BEST adopted, adapted, implemented, or hyperlinked by the organization is appreciated.

Please cite as: *Name of Team / Authors, Cincinnati Children's Hospital Medical Center: Best Evidence Statement Title, <http://www.cincinnatichildrens.org/service/j/anderson-center/evidence-based-care/recommendations/default/>, BEST number, pages 1-number, Date.*

This Best Evidence Statement has been reviewed against quality criteria by two independent reviewers from the CCHMC Evidence Collaboration.

Conflict of interest declaration forms are filed with the CCHMC EBDM group.

The BEST will be removed from the Cincinnati Children’s website, if content has not been revised within five years from the most recent publication date. A revision of the BEST may be initiated at any point that evidence indicates a critical change is needed.

Review History

| Date | Event | Outcome |
|-------------|-----------------------------|----------------------------------|
| | Original Publication | New BEST developed and published |

For more information about CCHMC Best Evidence Statements and the development process, contact the Evidence Collaboration at EBDMinfo@cchmc.org.

Note

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

APPENDIX: EVIDENCE SEARCH STRATEGY, RESULTS, & EVIDENCE TABLE**Criteria for considering studies for this review****Types of Studies**

Study designs which were considered for inclusion in the systematic review

Types of Participants

Patients/Population(s) which were considered for inclusion in the systematic review

(What populations were applicable to this review? For example, only pediatric studies were planned for inclusion.)

Types of Interventions

Interventions and Comparisons which were considered for inclusion in the systematic review

Types of Outcomes

Outcomes which were considered for inclusion in the systematic review

Exclusion Criteria, if any

Additional criteria for exclusion that go beyond simply the opposite of the inclusion criteria

Search Strategy

| Search Databases | Search Terms | Limits, Filters, & Search Date Parameters | Date of Most Recent Search |
|---|--|---|----------------------------|
| <input type="checkbox"/> MedLine <i>via PubMed or Ovid</i> | <ul style="list-style-type: none"> •X •X | Publication Dates or Search Dates: <ul style="list-style-type: none"> • mm/yyyy to mm/yyyy <input type="checkbox"/> English Language <input type="checkbox"/> Pediatric Evidence Only: <ul style="list-style-type: none"> •X <input type="checkbox"/> Other Limits or Filters: <ul style="list-style-type: none"> •X | mm/dd/yyyy |
| <input type="checkbox"/> CINAHL | <ul style="list-style-type: none"> •X | Publication Dates or Search Dates: <ul style="list-style-type: none"> • mm/yyyy to mm/yyyy <input type="checkbox"/> English Language <input type="checkbox"/> Pediatric Evidence Only: <ul style="list-style-type: none"> •X <input type="checkbox"/> Other: <ul style="list-style-type: none"> •X | mm/dd/yyyy |
| <input type="checkbox"/> Cochrane Database for Systematic Reviews | <ul style="list-style-type: none"> •X | Publication Dates or Search Dates: <ul style="list-style-type: none"> • mm/yyyy to mm/yyyy <input type="checkbox"/> English Language <input type="checkbox"/> Pediatric Evidence Only: <ul style="list-style-type: none"> •X <input type="checkbox"/> Other: <ul style="list-style-type: none"> •X | mm/dd/yyyy |
| <input type="checkbox"/> PsychInfo | <ul style="list-style-type: none"> •X | Publication Dates or Search Dates: <ul style="list-style-type: none"> • mm/yyyy to mm/yyyy <input type="checkbox"/> English Language <input type="checkbox"/> Pediatric Evidence Only: <ul style="list-style-type: none"> •X <input type="checkbox"/> Other: <ul style="list-style-type: none"> •X | mm/dd/yyyy |
| <input type="checkbox"/> Other: | <ul style="list-style-type: none"> •X | Publication Dates or Search Dates: <ul style="list-style-type: none"> • mm/yyyy to mm/yyyy <input type="checkbox"/> English Language <input type="checkbox"/> Pediatric Evidence Only: <ul style="list-style-type: none"> •X <input type="checkbox"/> Other: <ul style="list-style-type: none"> •X | mm/dd/yyyy |

Search Results & Methods

The initial search for evidence identified ### articles.
 ### articles met the inclusion criteria above.

Optional Information which may be included in the above statements:

articles were discarded, as they were duplicates (n=###) or not related to the clinical question of interest based on title (n=###) and abstract (n=###) review.

articles were reviewed in full text and critically appraised.

articles were excluded/discarded for the following reasons: XXX (n=###), XXX (n=###), XXX (n=###), or XXX (n=###).

Appendix 2 User Checklist

for developing and posting of a BEST

BEST Title:

Check each box, once item has been completed on the BEST Template.

- Title succinctly describes the topic.
[BEST Manual: Conclusion – Completing the Supporting Information (page 23)]
- Clinical question is presented in PICO format as a question.
[BEST Manual: Step 1 (page 7)]
- Target Population is defined.
[BEST Manual: Step 5 (page 15)]
- Discussion/Synthesis of Evidence demonstrates how the Body of Evidence informs the Clinical Question.
[BEST Manual: Step 4 (page 13)]
- Discussion of the quality, quantity, and consistency of the Body of Evidence is included.
[BEST Manual: Step 4 (page 13)]
- The supporting evidence is relevant to the recommendation statement(s).
[BEST Manual: Step 4 (page 13)]
- Dimensions for judging the strength of a recommendation have been appropriately considered, including Body of Evidence, health benefits, side-effects, risks, and others.
[BEST Manual: Step 5 (page 17)]
- Recommendation(s) is(are) adequately specific and actionable.
Notes are used to add clarity to the recommendation(s), if applicable.
[BEST Manual: Step 5 (page 15)]
- Citations are included with the recommendation(s) and note(s).
[BEST Manual: Step 5 (page 15)]
- Recommendation(s) is(are) easily identifiable and begin(s) with the appropriate recommendation phrase to signify the strength of the recommendation.
[BEST Manual: Step 5 (page 15)]
- Reference List is complete and references/citations are consistently formatted.
[BEST Manual: Step 5 (page 15)]
- All citations have been assigned a quality level, and level legend is present.
[BEST Manual: Step 3 (page 12)]

Implementation

- The potential resource implications of applying the recommendation(s) have been considered.
 - *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*
[BEST Manual: Conclusion – Putting Evidence Into Practice (Applicability & Feasibility Issues) (page 20)]
- Processes or tools have been identified which need to be developed, adapted, or revised for incorporation of the recommendation into practice.
 - *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*
[BEST Manual: Conclusion – Putting Evidence Into Practice (Applicability & Feasibility Issues) (page 20)]
- Relevant CCHMC Tools are identified (if any).
 - *If no documents, then “None were found.” under that section title.*
[BEST Manual: Step 2 (page 20)]
- Outcome Measures and Process Measures are identified with the rationale for each measure.
 - *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*
[BEST Manual: Conclusion – Putting Evidence Into Practice (Outcome Measures and Process Measures) (page 21)]

Supporting Information

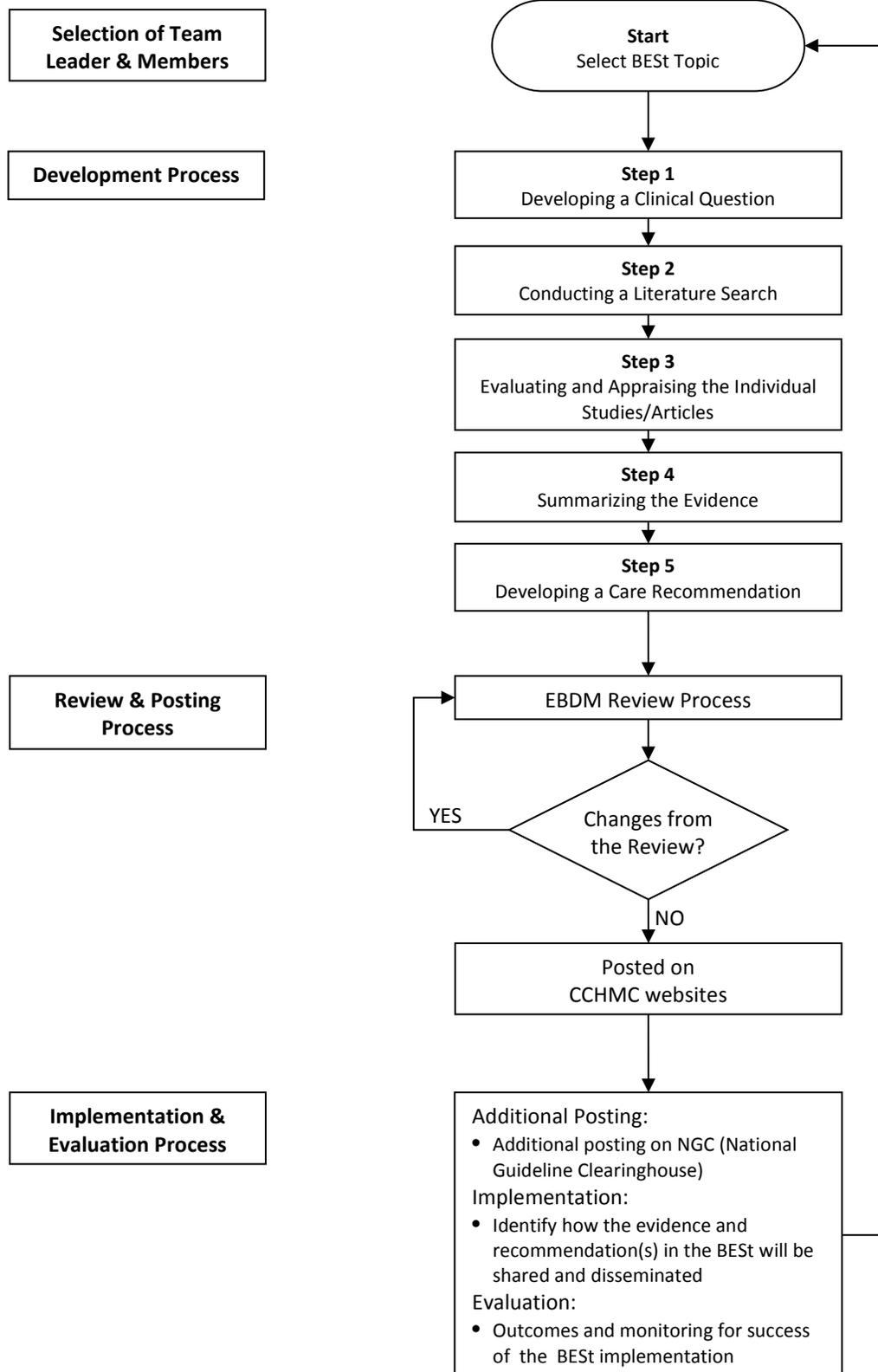
- The Background or Purpose of BEST Development provides rationale for choosing the topic.
[BEST Manual: Conclusion – Completing the Supporting Information (page 23)]
- Definitions provided as appropriate.
Mark any terms included in this section with an asterisk () where first used in the Clinical Question (PICO).*
[BEST Manual: Conclusion – Completing the Supporting Information (page 23)]
- Team member(s), including credentials, specialty and/or area of expertise is present, with a CCHMC employee listed as Team Leader/Author.
[BEST Manual: Conclusion – Completing the Supporting Information (page 24) ; Introduction (page 4)]
- Known Conflicts of Interest are declared by each team member.
[BEST Manual: Conclusion – Completing the Supporting Information (Conflict of Interest and Col form) (page 24)]

Appendix – Evidence Search Strategy, Results, & Evidence Table

- A priori Inclusion and Exclusion Criteria are defined – criteria for considering studies included for review.
[BEST Manual: TBD]
- Systematic search strategy is defined.
[BEST Manual: Step 2 (page 9)]
- Search results are defined – number of articles identified and number of articles included.
[BEST Manual: TBD]
- Evidence Table for Included Articles is provided – articles meeting inclusion criteria.
[BEST Manual: Step 4 (page 13)]

Submit completed BEST and User checklist to EBDMinfo@cchmc.org for quality review/posting by Evidence Collaboration.

Appendix 3 Overall Process Algorithm



Appendix 4 Beyond the Basics

Six Rules of Thumb to Improve Literature Search Success and Efficiency

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the topic being reviewed or developed. The search strategy may be revised to improve the output as needed.

| RULES OF THUMB | NOTES |
|--|---|
| Search only one database at a time. | <p>Because of differences in database design, one search strategy does not necessarily work for all databases.</p> <p>A possible exception is text-word-only searches, but even this is problematical in full-text databases like Cochrane’s DSR.</p> |
| Use MeSH (Medical Subject Headings). | <p>Because it is a controlled vocabulary applied by indexers on the basis of the actual content of the article, the MeSH terms describe the article and cover vagaries of the language better than text words and are, therefore, more reliable.</p> |
| | <p>MeSH is available for MEDLINE and CINAHL searches, but not (or only partially) for Cochrane searches.</p> |
| | <p>MM is available for EBSCO / CINAHL searches.</p> |
| Limit Cochrane searches to titles, abstracts, and keywords. | <p>Because Cochrane doesn’t use a controlled vocabulary, and also because of the comprehensive description of everything included and excluded for the systematic review, a search of the complete document gives an undesirably high proportion of irrelevant citations.</p> |
| Use Clinical Queries. | <p>Clinical Queries is a study design filter by domain.</p> |
| Use the age limit filters. | <p>Though these filters generally work better than text words, one disadvantage of this rule of thumb is that an age group which includes adolescents will include adult articles which have one or more adolescents in the study population.</p> |
| | <p>Text words can be additionally used, if further filtering is needed. When using text words, use all relevant permutations:</p> <ul style="list-style-type: none"> • infan\$ or infan* • child\$ or child* • pediatr\$ or pediatr* • paediatr\$ or paediatr* • neonat\$ or neonat* • teen\$ or teen* • adolesc\$ or adolesc* |
| Understand and use Boolean search operators. | <p>To keep it simple, use one type of operator per search and combine the search results thereafter. [<i>and, or, not</i>]</p> |

Appendix 5

Constructing a Search Strategy

Define the information need and state it in words as a question:

Expressing your information problem in words forces you to think about what you need and determine terms you will use in subsequent steps. For clinical questions remember the elements represented by the mnemonic device:

PICO (Population, Intervention, Comparison, Outcome)

- *For example:*
Among infants with cleft lip, are some feeding techniques or equipment more successful than others in providing necessary nutrition?

Break down the need into its component parts:

Extract the important concepts or keywords from the question.

- *For example:*
Using the question formulated above, the components are "cleft lip" and "feeding techniques or equipment" and "infants."

Identify synonyms for each concept:

Consult the thesaurus or vocabulary list for controlled vocabulary terms (subject headings or descriptors). The Medline thesaurus is called Medical Subject Headings or MeSH.

Consider whether a general term or a more specific term is appropriate.

- *For example:* *Would "bottle feeding" be more appropriate than the general term "feeding methods?"*

Often it is wise to use both controlled vocabulary terms and text words (*words used by the author in the title or abstract of an article*), and then combine the results of both searches.

Some concepts can be identified as specific aspects of primary concepts. They do not stand alone as search terms.

- *For example:* *Diagnosis, therapy, and etiology are aspects of a disease or condition.*
These aspects are best searched in Medline by applying subheading(s) to the primary search term.

Construct logical relationships between concepts:

The logical connectors are "AND," "OR," and "NOT."

- **"AND"** is used to connect terms that must both be in a record. "AND" narrows a search. Each time you add a term using "AND" you have narrowed the search another step.
- **"NOT"** is another way to narrow a search. "NOT" is used to eliminate records containing a given term.
- **"OR"** is used to connect or group synonyms. "OR" broadens a search.

Only one of the terms specified must be present in the record for a record to be selected.

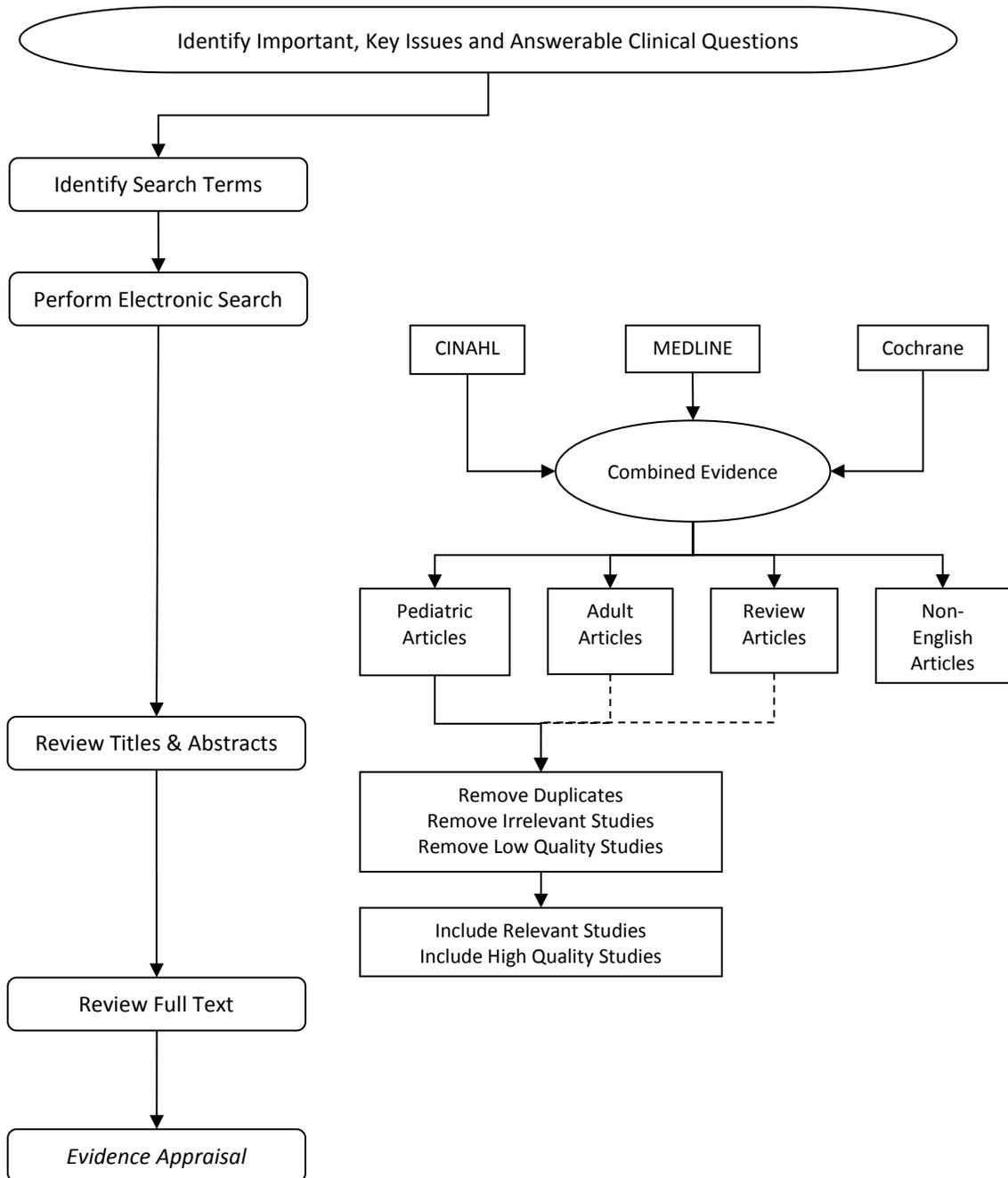
"Exploding" a term is a special instance of the "OR" connector that is used with databases such as Medline that use a hierarchically arranged thesaurus. You may retrieve specific and general terms in the hierarchy by using the "Explode" command.

Identify limiting features:

Aspects of the records may be used to limit retrieval. Common limiting aspects are age of subjects, language, species, publication type, or date of publication.

- *For example:* *You might search "cleft lip" AND "feeding methods," then limit the results to infants, English language, human, and 1990-2002. You could also limit by eliminating ("NOT") letters or reviews as publication types.*

Appendix 6 Literature Search Algorithm



Appendix 7 Evidence Tables

Evidence Table for Included Articles (i.e., articles meeting inclusion criteria)

| First Author & Year | Column Title | Evidence Level |
|---------------------|--------------|--------------|--------------|--------------|--------------|----------------|
| | | | | | | |
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Another Evidence Table Example

| TITLE, IF APPLICABLE | | | | | | | |
|----------------------|------------|---------------------------------|---------|----------|--------------|------------|----------|
| Study Citation | Study Type | N <small>Sample Size</small> | Setting | Patients | Intervention | Comparison | Outcomes |
| | Results | | | | Conclusions | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
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Appendix 8 Reviewer Checklist

for evaluating readiness for posting of a BEST

BEST Title:

| Met | Not Met | |
|-----|---------|--|
|-----|---------|--|

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 1. Clinical question is presented in PICO format as a question. <i>[BEST Manual: Step 1 (page 7)]</i> Comment: <u> </u> |
| <input type="checkbox"/> | <input type="checkbox"/> | 2. Target Population is defined. <i>[BEST Manual: Step 5 (page 15)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 3. Discussion/Synthesis of Evidence demonstrates how the Body of Evidence informs the Clinical Question. <i>[BEST Manual: Step 4 (page 13)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 4. Discussion of the quality, quantity, and consistency of the Body of Evidence is included. <i>[BEST Manual: Step 4 (page 13)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 5. The supporting evidence is relevant to the recommendation statement(s). <i>[BEST Manual: Step 4 (page 13)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 6. Dimensions for judging the strength of each recommendation have been appropriately considered, including Body of Evidence, health benefits, side-effects, risks, and others. <i>[BEST Manual: Step 5 (page 17)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 7. Recommendation(s) is(are) adequately specific and actionable. <i>Notes are used to add clarity to the recommendation(s), if applicable.</i> <i>[BEST Manual: Step 5 (page 15)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 8. Citations are included with the recommendation(s) and note(s). <i>[BEST Manual: Step 5 (page 15)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 9. Recommendation(s) is(are) easily identifiable and begin(s) with the appropriate recommendation phrase to signify the strength of the recommendation. <i>[BEST Manual: Step 5 (page 15)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 10. Reference List is complete and references/citations are consistently formatted. <i>[BEST Manual: Step 5 (page 15)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 11. All citations have been assigned a quality level, and level legend is present. <i>[BEST Manual: Step 3 (page 12)]</i> Comment: Click here to enter text. |

Implementation

| Met | Not Met | |
|-----|---------|--|
|-----|---------|--|

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 12. The potential resource implications of applying the recommendation(s) have been considered. <ul style="list-style-type: none"> • <i>If no recommendation is made (e.g., insufficient evidence), then this section will not apply.</i> <i>[BEST Manual: Conclusion – Putting Evidence Into Practice (Applicability & Feasibility Issues) (page 20)]</i> Comment: Click here to enter text. |
| <input type="checkbox"/> | <input type="checkbox"/> | 13. Processes or tools have been identified which need to be developed, adapted, or revised for incorporation of the recommendation into practice. <ul style="list-style-type: none"> • <i>If no recommendation is made (e.g., insufficient evidence), then this section will not apply.</i> <i>[BEST Manual: Conclusion – Putting Evidence Into Practice (Applicability & Feasibility Issues) (page 20)]</i> Comment: Click here to enter text. |

14. Outcome Measures and Process Measures are identified with the rationale for each measure.
- *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*
- [BEST Manual: Conclusion – Putting Evidence Into Practice (Outcome Measures and Process Measures) (page 21)]*
Comment: [Click here to enter text.](#)

Supporting Information

Met Not Met

15. Team member(s), including credentials, specialty and/or area of expertise is present, with a CCHMC employee listed as Team Leader/Author.
- [BEST Manual: Conclusion – Completing the Supporting Information (Group/Team Members) (page 24); Introduction (page 4)]*
Comment: [Click here to enter text.](#)
16. Known Conflicts of Interest are declared by each team member.
- [BEST Manual: Conclusion – Completing the Supporting Information (Conflict of Interest and Col form) (page 24)]*
Comment: [Click here to enter text.](#)

Appendix – Evidence Search Strategy, Results, & Evidence Table

Met Not Met

17. *A priori* Inclusion and Exclusion Criteria are defined – criteria for considering studies included for review.
- [BEST Manual: TBD]*
Comment: [Click here to enter text.](#)
18. Systematic search strategy is defined.
- [BEST Manual: Step 2 (page 9)]*
Comment: [Click here to enter text.](#)
19. Search results are defined – number of articles identified and number of articles included.
- [BEST Manual: TBD]*
Comment: [Click here to enter text.](#)
20. Evidence Table for Included Articles is provided – articles meeting inclusion criteria.
- [BEST Manual: Step 4 (page 13)]*
Comment: [Click here to enter text.](#)

21. I, the reviewer, was not involved with the development of this BEST.
- Comment: [Click here to enter text.](#)*

- Meets all criteria (*may be posted*)
- Does not meet all criteria (*return to EBDMinfo@cchmc.org for required changes*)

BEST is attached with tracked changes: Yes No, not attached

Additional Comments / Suggestions: [Click here to enter text.](#)

[Click here to enter text.](#)
Reviewers' Names

[Click here to enter text.](#)
Date Reviewed

Appendix 9

Conflict of Interest Disclosure

In accordance with IOM (Institute of Medicine) and AGREE (Appraisal of Guidelines for Research and Evaluation) criteria, development Team members and key professional support staff must declare whether they have any conflict of interest. Any situation that would or would be perceived as capable of influencing the decision for any recommendation within the evidence work is considered a conflict.

Name: _____ Credentials (e.g. RN, MD): _____

Division: _____

Title or Topic of Guideline or Best Evidence Statement: _____

Role on Proposal: Team Member

Key Professional Support Staff (e.g. members of Evidence Collaboration)

Please check all that apply:

- A. **No significant financial interests* exist** related to this Evidence-Based Care Guideline (EBCG) or Best Evidence Statement (BEST) development or revision which would require a disclosure.

- B. **No significant intellectual interests exist** related to this Evidence-Based Care Guideline (EBCG) or Best Evidence Statement (BEST)

- C. **A disclosure is required.** I hereby disclose the following significant interest(s): *(Check all that apply)*
 - Salary or other payment for services (e.g., consulting fees or honoraria, royalties)
 - Equity interests (e.g., stocks, stock options, or other ownership interests)
 - Other significant financial interests that could possibly affect or be perceived to affect the specific EBCG or BEST development, implementation or reporting activities
 - Intellectual interests (e.g., patents, copyrights, authorship of article or research involvement that bears directly on recommendations, influence of expertise)
 - Other interests pertinent to the potential scope of these activities (e.g., non-commercial, institutional, and patient/public activities)

If C is checked, you must attach a signed, written statement (in an envelope marked "Confidential") identifying the business entity involved, the nature/type of the interest, and the amount of the interest that is related to the specific EBCG or BEST development, implementation or reporting activities.

- I attest that I have listed all relevant financial, intellectual, professional, and personal conflicts that have occurred within the previous 12 months and that I will immediately update this information if changes occur.
By checking this box, I agree to the terms of this electronic disclosure.

Signature (please type your signed name): _____
Date: _____

Send completed form via e-mail to EBDMinfo@cchmc.org.

* Financial Interest does not include:

1. Salary, royalties, or other remuneration received directly from CCHMC.
2. Equity interests that, when aggregated for the Covered Individual and his/her family, do not exceed \$5,000 in fair market value and do not represent a five (5) percent or greater ownership interest in a single entity.
3. Salary, royalties, or other payments that, when aggregated for the Covered Individual and his/her Family are not expected to exceed \$5,000 in the prior or next twelve (12) months.
4. Interests arising solely by reason of investment by mutual, pension, or other institutional investment funds over which the Covered Individual does not exercise control.
5. Royalties for publishing scholarly works or other writings.